TENNESSEE GENERAL ASSEMBLY
FISCAL REVIEW COMMITTEE

FISCAL MEMORANDUM

HB 317 – SB 582

April 1, 2013

SUMMARY OF ORIGINAL BILL: Expands the current definitions for "compounding" and "dispense" in statute relative to pharmacy practice. Authorizes drugs to be compounded for use in a practitioner's office or licensed health care facility, and be prescribed to the patients of any such practitioner or licensed health care facility.

FISCAL IMPACT OF ORIGINAL BILL:

NOT SIGNIFICANT

SUMMARY OF AMENDMENTS (005749, 005608): Authorizes drugs be compounded for use in a licensed practitioner's office, licensed health care facility, or by emergency medical services for the patients of such practitioners, facilities, and services. Requires any pharmacy which is located outside this state to provide proof of licensure from the regulatory entity within the state in which the pharmacy is physically located prior to initial licensure in this state as a compounding pharmacy. Such licensure provided from the pharmacy's state must have been issued or renewed within the previous twelve months. The Board of Pharmacy holds the right to require any additional information prior to issuing a license to a compounding licensure outside this state. Requires any active state-licensed compounding pharmacy to notify the Board of Pharmacy, within fourteen days of receipt of any order or decision by a regulatory agency other than the Board, when a disciplinary action or warning has been imposed upon the pharmacy. Requires any pharmacies engaged in sterile compounding to comply with relevant United State Pharmacopeia (USP) guidelines as adopted by the Board, and further requires such pharmacies, except hospital pharmacies compounding for patients of a hospital, to quarterly report the Board the quantity of sterile compounded products dispensed in a defined time period and in accordance with rules or policies of the Board; however, the executive director of the Board may request this information from a hospital pharmacy for cause and the hospital is required to respond in a timely manner, as defined by the executive director..

FISCAL IMPACT OF BILL WITH PROPOSED AMENDMENTS:

Unchanged from the original fiscal note.

Assumptions for the bill as amended:

- According to the Department of Health, allowing a pharmacy to compound drugs and dispense such drugs to patients would, by definition, be distribution, which under current statute requires a manufacturer's license, which is separate and apart from a pharmacy license.
- A registration fee of $50 applies to anyone seeking to become a pharmacist. A pharmacist license costs $96 every two years.
- A registration fee of $168 is applicable to any entity seeking a manufacturer/wholesaler/distributor (MWD) license. A MWD license costs $408 every two years.
- This act may result in any number of current MWD licensees renewing as a pharmacist license due a lower cost for licensure but due to the difficulty of determining what companies currently have both licenses, an exact impact cannot be determined. It is reasonably estimated that any decrease will not be significant.
- Any costs incurred due to additional regulatory responsibilities or rulemaking as required by the Board can be accommodated within existing resources.
- Pursuant to Tenn. Code Ann. § 4-3-1011, all regulatory boards are required to be self-supporting over a two-year period. The Board of Pharmacy had closing balances of $553,901 in FY10-11, $85,209 in FY11-12, and a closing reserve balance of $929,407 on June 30, 2012.

CERTIFICATION:

The information contained herein is true and correct to the best of my knowledge.

Lucian D. Geise, Executive Director

/jdb